

**REMARKS**

Applicant has amended claims 40, 45-47 and cancelled claim 44. Claims 40-43, 45-47 are pending with the present amendments. The amended claims are directed to one embodiment of the present invention, and Applicant may pursue claims of equal, broader or lesser scope in a related application. The claims, as amended, specifically recited the step of monitoring culture medium in which the monolayer is grown for production of soluble secreted factors indicative of a disease state or lack thereof. This amendment is supported in the specification at page 13, lines 21-37. No new matter has been added.

Applicant addresses the rejections below inasmuch as they may apply to the claims as amended.

**1. The Rejection Under 35 U.S.C. § 102(b)**

The Office action rejected claims 40-44 under 35 U.S.C. § 102(b) as being anticipated by Kornblith, (J Neurosurg) entitled "Variations in Response of Human Brain Tumors to BCNU in vitro" ("Kornblith").

Anticipation under 35 U.S.C. § 102 requires that a single reference teach each and every element of a claim. Verdegaal Bros. v. Union Oil Co. of California, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Any feature not directly taught must be inherently present. MPEP 706.02.

Kornblith reports an *in vitro* method to monitor the response of individual patient's tumor cells to 1,3-bis(2-chloroethyl)-1-nitrosourea (BCNU). Applicant's amended claims expressly recite the step of monitoring the culture monolayer for the production of soluble secreted factors. Kornblith entirely fails to teach the step of monitoring for soluble secreted factors. Indeed, the method employed in Kornblith assesses only the response of cells to one specific agent and does

not take into account soluble factors. As such, Kornblith does not anticipate Applicant's amended claims. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

**2. The Rejection Under 35 U.S.C § 103(a)**

The Office action rejected claims 45-47 as being unpatentably obvious over Kornblith. In particular, the Office action suggests that Kornblith discloses the use of a chemotherapeutic agent and infers that it would have been obvious to "specify the type of agent" and "to test any known cytotoxic compounds for their know effects." Applicant has amended claims 45-47 to correct claim dependencies.

To establish a prima facie case of obviousness, the prior art (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and a reasonable expectation of success must be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j).

Applicant's claims 45-47 expressly recite a method of monitoring culture medium for the production of soluble secreted factors. The Office action suggests that "a change in secreted factors ... would be expected to reflect the condition of the cells." Kornblith, however, entirely fails to disclose or suggest a method for monitoring soluble secreted factors. Furthermore, the Examiner has not cited any art, nor is the Applicant aware of any art that suggests monitoring the culture medium for soluble secreted factors since the publication of the Kornblith reference in 1978. Applicant's claims, therefore, are not obvious in light of Kornblith. Accordingly,

Applicant respectfully requests that the rejections under 35 U.S.C § 103 should be reconsidered and withdrawn.

**3. Related Applications**

The Examiner requested that Applicant supply a list of all related cases, allowed, pending or abandoned. The following is a list as requested:

<b>Number</b>	<b>Title</b>	<b>Filed</b>	<b>Issued</b>
U.S. Patent No. 5,728,541	"Method of Preparing Cell Cultures From Biological Specimens for Chemotherapeutic and Other Assays"	12-Jul-1996	17-Mar-1998
U.S. Patent No. 6,416,967	"Method for Using Multicellular Particulates to Analyze Malignant or Hyperproliferative Tissue"	10-Nov-1998	08-Jul-2002
U.S. Serial No. 09/040,161	"Method for Preparing Cell Cultures from Biological Specimens for Chemotherapeutic and Other Assays"	17-Mar-1998	n/a
U.S. Serial No. 10/205,887	"Method for Preparing Cell Cultures From Biological Specimens for Chemotherapeutic and Other Assays"	26-Jul-2002	n/a
U.S. Serial No. 09/039,957	"Method for Culturing and Assaying Cells"	16-Mar-1998	n/a
U.S. Serial No. 09/095,993	"Staining Agents and Protocols for Characterizing Malignant Cells in Culture"	11-Jun-1998	n/a
U.S. Serial No. 09/691,492	"Method for Genetic Analysis of Proliferating Cells"	18-Oct-2002	n/a
U.S. Serial No. 10/399,563	"Method for Tandem Genomic/ Proteomic Analysis of Proliferating Cells"	17-Apr-2003	n/a
U.S. Serial No. 10/208,480	"Method for Preparing Cell Cultures From Biological Specimens for Chemotherapeutic and Other Assays"	30-Jul-2002	n/a
U.S. Serial No. 10/336,659	"Method for Analyzing the Effectiveness of a Chemotherapeutic Agent"	02-Jan-2003	n/a

4. **Prior Art Made of Record But Not Relied Upon**

As recognized by the Examiner, U.S. Patent No. 5,728,541, U.S. Patent No. 6,416,967 and Kornblith (Clin Neurosurgery) entitled "Role of Tissue Culture in Prediction of Malignancy" do not teach or suggest the invention claimed by the Applicants.

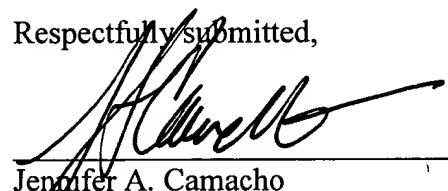
**CONCLUSION**

Applicant submits that on the basis of the foregoing remarks and claim amendments, claims 40-47 are in condition for allowance. Should any further issues of anticipation or patentability be determined to exist, the Examiner is invited to contact the undersigned by telephone to expedite the favorable prosecution of this application.

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Respectfully submitted,



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